REMARKS

Claims 1-42 are pending, and new claims 43-46 have been added. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

Rejections under 35 U.S.C. 103(a)

Claims 1-42 stand rejected under 35 U.S.C. 103(a), over PCT Patent No. 99/18967 to Iversen (the Iversen Patent). Applicant respectfully traverses the rejection.

Subject Application

The present invention relates to a method of treatment of a patient undergoing analgesic therapy by administering a therapeutically effective amount of an opioid analgesic whilst minimizing the side effects of the opioid by the separate, simultaneous or sequential administration of a therapeutically effective amount of devazepide.

PCT Patent No. 99/18967 to Iversen (the Iversen Patent)

In contrast, PCT Patent No. 99/18967 to Iversen (the Iversen Patent) is directed to pharmaceutical formulations suitable for treating pain, in particular, neuropathic pain and/or dysesthesia, and their preparation. The formulations typically comprise a cholecystokinin antagonist and an opioid. Specifically, the formulation comprises an opioid-potentiating amount of a CCK antagonist, an analgesic amount of an opioid; and a pharmaceutically acceptable biphasic carrier, which comprises an organic phase comprising a glyceride derivative and a hydrophilic phase. (page 2, lines 21-28) Devazepide is of course a CCK antagonist, as described in the present application.

Claims 1-42 are in Condition for Allowance

Under 35 U.S.C. &103(a) over Iversen

Claims 1-42 were rejected under 35 U.S.C. §103(a) over Iversen. Applicant respectfully traverses.

The present invention discloses a method of treatment of a patient undergoing opioid analgesic therapy which comprises mitigating the side effects of the opioid by the administration of a therapeutically effective amount of devazepide.

In contrast, the Iversen Patent discloses pharmaceutical formulations suitable for treating pain, comprising cholecystokinin antagonist and an opioid. Specifically, the use of devazepide avoids the need to increase dosages of opioids to unacceptable levels. However, the fact that devazepide mitigates the undesirable side effects of opioids per se, is distinct from devazepide's opioid potentiating effect.

Therefore, the present invention is not obvious in light of the Iversen Patent because it does not teach the use of devazepide to reduce the side effects of the opioid while increasing it's analgesic effect. Consequently, the Iversen Patent would teach away from the present invention since its teaching would be such that opioid side effects could only be minimized with devazepide due to its opioid potentiating effect. Thus, a person of skill in the art, faced with a desire to minimize opioid side effects would administer a lower dose of the opioid with devazepide. However, it would not be apparent to one of skill in the art, that a higher dose of opioid could be utilized while still achieving a reduction in the opioid side effects. Thus, the present invention offers the patient a reduction in side effects while effectively increasing the analgesic effect of the opioid. Such an advantage is neither disclosed nor taught by Iversen.

Thus, for the reasons set forth, claims 1-42 are not obvious over the Iversen Patent, and are in condition for allowance.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters which need to be discussed in order to expedite the prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No 50-170, referencing our Docket No. 330499.00007.

Respectfully submitted,

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Date: September 2, 2003